# **News Release**



## Kamada Reports First Quarter 2015 Financial Results

Introduces 2015 Revenue Guidance

Conference call begins today at 8:30 a.m. Eastern time

**NESS ZIONA, Israel (May 12, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA),** a plasma-derived protein therapeutics company focused on orphan indications, announces financial results for the three months ended March 31, 2015.

Financial highlights of the 2015 first quarter included:

- Total revenues of \$9.0 million compared with \$13.2 million for the first quarter of 2014;
- Gross profit of \$0.4 million compared with \$3.3 million in the year-ago first quarter; and
- Adjusted net loss of \$4.8 million compared with an adjusted net loss of \$2.0 in the year-ago first quarter.

Other highlights of the 2015 first quarter and recent weeks included:

- Announced additional results from the European Phase 2/3 clinical trial of the Company's inhaled AAT to treat AAT deficiency (AATD), which showed clinically and statistically significant improvement in lung function and improvements in quality-of-life parameters;
- Awarded European Orphan Drug Designation for AAT to treat Graft-versus-Host disease (GvHD);
- Announced that effective July 1<sup>st</sup>, 2015 David Tsur, co-founder and Chief Executive Officer, will become Deputy Executive Chairman of the Board, and Amir London, currently Senior Vice President of Business Development, will become Chief Executive Officer and Gil Efron, currently Chief Financial Officer, will take on the added role of Deputy Chief Executive Officer; and
- Strengthened the senior leadership team with the appointment of Eran Schenker, M.D. as Vice President-Medical Director.

## **Management Commentary**

"We made progress during the first quarter across a number of key areas, specifically with regard to advancing our program for inhaled AAT. We continued to build our core protein plasma business despite Proprietary Product revenue being impacted by a delay in the release of product batches as we awaited final validation of a filling process. This process was validated in April and the delayed revenue from the first quarter will be realized in the second quarter of 2015 and gross profit is expected to return to levels gained in prior quarters. As a result, we remain confident in our ability to achieve our revenue targets for 2015 as well our 2017 revenue goal of \$100 million, which includes approximately 75% growth in the Proprietary Products Segment. Increases in the number of patients treated by Glassia are on track through the quarter to meet our target to double the number of patients treated by our intravenous AAT world wide by 2018," stated David Tsur, co-founder and Chief Executive Officer of Kamada."

"Our relationship with Baxter, our U.S. strategic partner for Glassia®, remains strong as we collaborate to grow sales and expand use to other indications of unmet medical need. We are pleased with the consistently increasing number of patients treated by Glassia. We expect this growth to accelerate in the coming years and to remain a strong contributor to our revenue growth."

"We were especially pleased to report final results from our European Phase 2/3 clinical study, which showed clinically and statistically significant improvements in spirometric measures of lung function, particularly in bronchial airflow measurements  $FEV_1$  (L),  $FEV_1$ % predicted and  $FEV_1$ /SVC. These favorable results were even more pronounced when analyzing the overall treatment effect throughout the full year."

"Lung functions are the gold standard measurement for pulmonary disease, and along with symptom improvements and the safety profile of the product, these data support our decision to submit a Marketing Authorization Application with the European Medicines Agency for our inhaled AAT therapy to treat AATD patients. We expect to make this filing by year-end 2015."

"We remain pleased with the ongoing favorable data generated from clinical development programs with our intravenous AAT to treat newly diagnosed type 1 diabetes and GvHD, both orphan indications with significant unmet medical need. These results are encouraging us to pursue this opportunity. In addition to these ongoing studies, we plan to initiate a Phase 2 proof-of-concept study with intravenous AAT to treat patients undergoing lung transplantation."

"We look forward to achieving a number of important milestones throughout the balance of 2015. We expect strong second quarter revenue along with continued clinical progress in various programs to strengthen our Company and enhance shareholder value," concluded Mr. Tsur.

### **First Quarter Financial Results**

Total revenues for the first quarter of 2015 were \$9.0 million compare with \$13.2 million for the first quarter of 2014. Revenue from the Proprietary Products Segment was \$3.2 million compared with \$7.4 million in the year-ago quarter, due to a delay in the release of product batches as the Company awaited final validation of a filling process. This process was validated in April and the Company expects delayed revenue from the first quarter 2015 to be realized in the second quarter of 2015. Revenue from the Distributed Product Segment remained steady at \$5.8 million for the first quarters of 2015 and 2014.

Gross profit for the first quarter of 2015 was \$0.4million compared with \$3.3 million for the first quarter of 2014. Gross margin declined to 4% from 25% in the first quarter of 2014. The decline was a result of lower Proprietary Product revenue for reasons stated earlier and to changes during the quarter in foreign exchange rates in the Distributed Product Segment.

Research and development expenses in the first quarter of 2015 were \$3.6 million, up from \$3.4 million in the first quarter of 2014 as the company continued to support various clinical studies including three key clinical trials and the closing and analysis of the European Phase 2/3 study of inhaled AAT.

Selling, general and administrative expenses in the first quarter of 2015 of \$2.5 million decreased modestly from \$2.6 million in the first quarter of 2014.

For the first quarter of 2015, the Company reported an operating loss of \$5.8 million compared with an operating loss of \$2.7 million for the first quarter of 2014. The Company recorded a net loss for the first quarter of 2015 of \$5.3 million or \$0.15 per share, compared with a net loss of \$3.1 million or \$0.09 per share for the same period in 2014. The adjusted net loss for the first quarter of 2015 was \$4.8 million compared with an adjusted net loss of \$2.0 million for the same period in 2014.

Adjusted EBITDA for the first quarter of 2015 was a loss of \$4.5 million compared with a loss of \$1.0 million for the first quarter of 2014.

### **Balance Sheet Highlights**

As of March 31, 2015, Kamada had cash, cash equivalents and short-term investments of \$49.7 million, compared with \$51.9 million as of December 31, 2014. During the first quarter of 2015, the Company used \$2.0 million in cash to fund operations and \$0.5 million for capital expenditures.

### 2015 Revenue Guidance

For the year ending December 31, 2015, Kamada expects total revenue to be between \$70 million and \$73 million, with revenue from its Distributed Product Segment projected to be between \$26 million and \$28 million and revenue from its Proprietary Products Segment projected to be between \$45 million and \$47 million. The Company notes that revenue projections for 2015 take into account an expected negative foreign exchange impact of approximately \$2.0 million in relation to product sales in Israel and Russia, and presume that U.S. revenue from the agreement with Baxter remains on track.

### **Conference Call**

Kamada management will host an investment community conference call today at 8:30 a.m. Eastern time to discuss these results and answer questions. Shareholders and other interested parties may participate in the conference call by dialing 888-803-5993 (from within the U.S.), 706-634-5454 (from outside the U.S.) or 1-809-315-362 (toll-free from Israel) and entering the conference identification number: 44127836.

A replay of the call will be accessible beginning two hours after its completion through May 18, 2015 by dialing 855-859-2056 (from within the U.S.) or 404-537-3406 (from outside the U.S.) and entering the conference identification number: 44127836. The call will also be archived for 90 days at <a href="https://www.streetevents.com">www.streetevents.com</a> and <a href="https://www.kamada.com">www.kamada.com</a>.

#### **About Kamada**

Kamada Ltd. is focused on plasma-derived protein therapeutics for orphan indications, and has a commercial product portfolio and a robust late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other AAT is a protein derived from human plasma with known and newlyplasma-derived proteins. discovered therapeutic roles given its immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties. The Company's flagship product is Glassia<sup>®</sup>, the first and only liquid, ready-touse, intravenous plasma-derived AAT product approved by the U.S. Food and Drug Administration. Kamada markets Glassia in the U.S. through a strategic partnership with Baxter International. In addition to Glassia, Kamada has a product line of nine other injectable pharmaceutical products that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America, Eastern Europe and Asia. Kamada has five late-stage plasma-derived protein products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency that completed pivotal Phase 2/3 clinical trials in Europe and entered Phase 2 clinical trials in the U.S. Kamada also leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing 10 complementary products in Israel that are manufactured by third parties.

### **Cautionary Note Regarding Forward-Looking Statements**

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions and results related to financial results forecast, commercial results, timing and results of clinical trials and EMA and U.S. FDA authorizations. Forward-looking statements are based on Kamada's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several

factors including, but not limited to, unexpected results of clinical trials, delays or denial in the U.S. FDA or the EMA approval process, additional competition in the AATD market or further regulatory delays. The forward-looking statements made herein speak only as of the date of this announcement and Kamada undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

## **Contacts:**

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-Tables to Follow-

	As of March 31,		As of December 31,		
	2015	2014	2014		
	Unau	dited	Audited		
		In thousands			
<u>Current Assets</u>					
Cash and cash equivalents	\$ 13,011	\$ 33,314	\$ 14,546		
Short-term investments	36,693	38,811	37,350		
Trade receivables	8,863	12,592	17,514		
Other accounts receivables	2,954	3,284	2,359		
Inventories	27,435	28,614	25,423		
	88,956	116,615	97,192		
Property, plant and equipment, net	21,523	21,384	21,769		
Other long-term assets	110	262	179		
	21,633	21,646	21,948		
	110,589	138,261	119,140		
Current Liabilities					
Short term credit and Current maturities of					
convertible debentures	7,411	8,678	7,492		
Trade payables	13,376	16,321	16,530		
Other accounts payables	3,493	3,750	4,045		
Deferred revenues	2,799	5,431	2,919		
	27,079	34,180	30,986		
Non-Current Liabilities					
Convertible debentures	-	7,686	-		
Employee benefit liabilities, net	739	801	722		
Deferred revenues	6,958	7,683	7,015		
	7,697	16,170	7,737		
Equity Share capital	9,227	9,201	9,208		
Share premium	158,893	157,117	158,417		
Conversion option in convertible debentures	1,147	2,217	1,147		
Capital reserve due to translation to	1,11,	2,217	1,117		
presentation currency	(3,490)	(3,490)	(3,490)		
Capital reserve from hedges Capital reserve from available for sale	(265)	87	(116)		
financial assets	128	12	10		
Capital reserve from share-based payments	9,009	6,266	8,783		
Capital reserve from employee benefits	(81)	(129)	(81)		
Accumulated deficit	(98,755)	(83,370)	(93,461)		
	75,813	87,911	80,417		
	_	_			
	\$ 110,589	\$ 138,261	\$ 119,140		
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	Three	Three months period Ended March, 31			Year ended December 31	
	20	2015 2014			2014	
		Unaudited		A	udited	
		In thousands				
Revenues from proprietary products Revenues from distribution	\$	3,173 5,757	\$	7,421 5,766	\$	44,389 26,676
Total revenues		8,930		13,187		71,065
Cost of revenues from proprietary products Cost of revenues from distribution		3,295 5,243		5,003 4,922		32,617 23,406
Total cost of revenues		8,538		9,925		56,023
Gross profit		392		3,262		15,042
Research and development expenses		3,643		3,365		16,030
Selling and marketing expenses		799		647		2,898
General and administrative expenses		1,700		1,957		7,593
Operating loss		(5,750)		(2,707)		(11,479)
Financial income Income in respect of currency exchange and		182		243		1,611
translation differences and derivatives instruments, net		513		39		_
Financial expense		(239)		(674)		(3,293)
Loss before taxes on income	-	(5,294)		(3,099)		(13,161)
Taxes on income		<u>-</u>		23		52
Net loss		(5,294)		(3,122)		(13,213)
Other Comprehensive loss: Items that may be reclassified to profit or loss in subsequent periods:						
Gain on available for sale financial assets		118		39		37
Profit (loss) on cash flow hedges  Net amounts transferred to the statement of profit or		(221)		29		(162)
loss for cash flow hedges		72		(98)		(110)
Items that will not be reclassified to profit or loss in subsequent periods:						
Actuarial gain from defined benefit plans						48
Total comprehensive loss	\$	(5,325)	\$	(3,152)	\$	(13,400)
Loss per share attributable to equity holders of the Company:						
Basic loss per share	\$	(0.15)	\$	(0.09)		\$ (0.37)
Diluted loss per share	\$	(0.15)	\$	(0.09)		\$ (0.37))
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:	35	5,993,130	35,	960,487	3	35,971,335

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three months Mar	Year Ended December 31,			
	2015	2014			
	Una	Audited			
		In thousands			
Cash Flows from Operating Activities					
Net loss	\$ (5,294)	\$ (3,122)	\$ (13,213)		
Adjustments to reconcile loss to net cash used in operating activities:					
Adjustments to the profit or loss items:					
Depreciation and amortization	771	663	2,788		
Finance expenses, net	(447)	392	1,682		
Cost of share-based payment	505	1,086	3,751		
Taxes on income	-	23	52		
Loss from sale of property and equipment	-	-	(2)		
Change in employee benefit liabilities, net	17	(26)	(57)		
	846	2,138	8,214		
Changes in asset and liability items:					
Decrease (increase) in trade receivables	8,418	5,236	(869)		
Increase in other accounts receivables	(829)	(240)	(50)		
Increase in inventories	(2,012)	(6,681)	(3,490)		
Decrease in deferred expenses	71	559	1,209		
Decrease (increase) in trade payables	(2,572)	2,241	3,261		
Decrease in other accounts payables	(659)	(563)	(344)		
Decrease in deferred revenues	(177)	(846)	(4,026)		
	2,240	(294)	(4,309)		
Cash paid and received during the period for:					
Interest paid	(121)	(301)	(1,210)		
Interest received	350	94	758		
Taxes paid	(29)	(60)	(158)		
	200	(267)	(610)		
Net cash used in operating activities	\$ (2,008)	\$ (1,545)	\$ (9,918)		

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three months period Ended March 31				Year Ended December 31		
	2015 2014			2014			
_	Unaudited				Audited		
_			In th	ousands			
Cash Flows from Investing Activities Short-term investments Purchase of property and equipment Proceeds from sale of property and equipment	\$	425 (509)	\$	(23,432) (616)	\$	(23,746) (3,076) 3	
Net cash used in investing activities		(84)		(24,048)		(26,819)	
Cash Flows from Financing Activities Exercise of warrants and options into shares Short term credit from bank and others, net Repayment of convertible debentures Net cash provided by (used in) financing activities		- - -		- - -		88 (7,728)	
Exchange differences on balances of cash and cash equivalent		557		(203)		(7,640)	
Decrease in cash and cash equivalents		(1,535)		(25,796)		(44,564)	
Cash and cash equivalents at the beginning of the year		14,546		59,110		59,110	
Cash and cash equivalents at the end of the period	\$	13,011	\$	33,314	\$	14,546	
Significant non-cash transactions							
Exercise of convertible debentures into shares	\$	<u> </u>	\$	7	\$	7	
Exercise of options into shares	\$	216	\$	_	\$		

## **Adjusted EBITDA**

	Three months Ended Mar	For the year Ended December 31			
-	2015	2014	2014		
- -	Thousands of US dollar				
Net income (loss)	\$ (5,294)	\$ (3,122)	\$ (13,213)		
Income tax expense	-	23	52		
Financial expense, net	57	431	1,682		
Depreciation and amortization expense	771	663	2,788		
Share-based compensation charges	505	1,086	3,751		
Income in respect of translation differences and derivatives instruments, net	(513)	(39)	-		
Adjusted EBITDA	\$ (4,474)	\$ (958)	\$ (4,940)		

## Adjusted net income

	Three months period Ended March 31		For the year Ended December 31		
	2015	2014	2014		
	Thousands of US dollar				
Net income (loss)	\$ (5,294)	\$ (3,122)	\$ (13,213)		
Share-based compensation charges	505	1,086	3,751		
Adjusted EBITDA	\$ (4,789)	\$ (2,036)	\$ (9,462)		